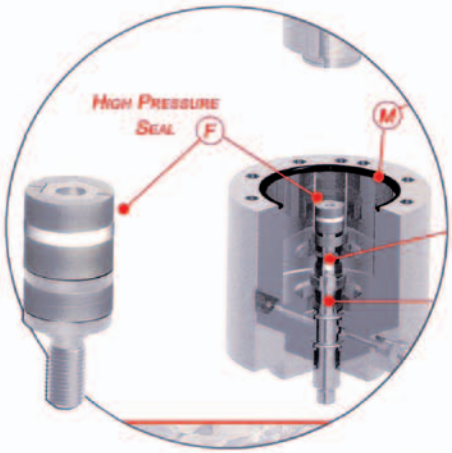
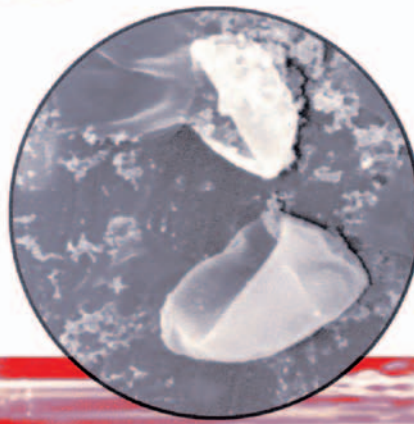
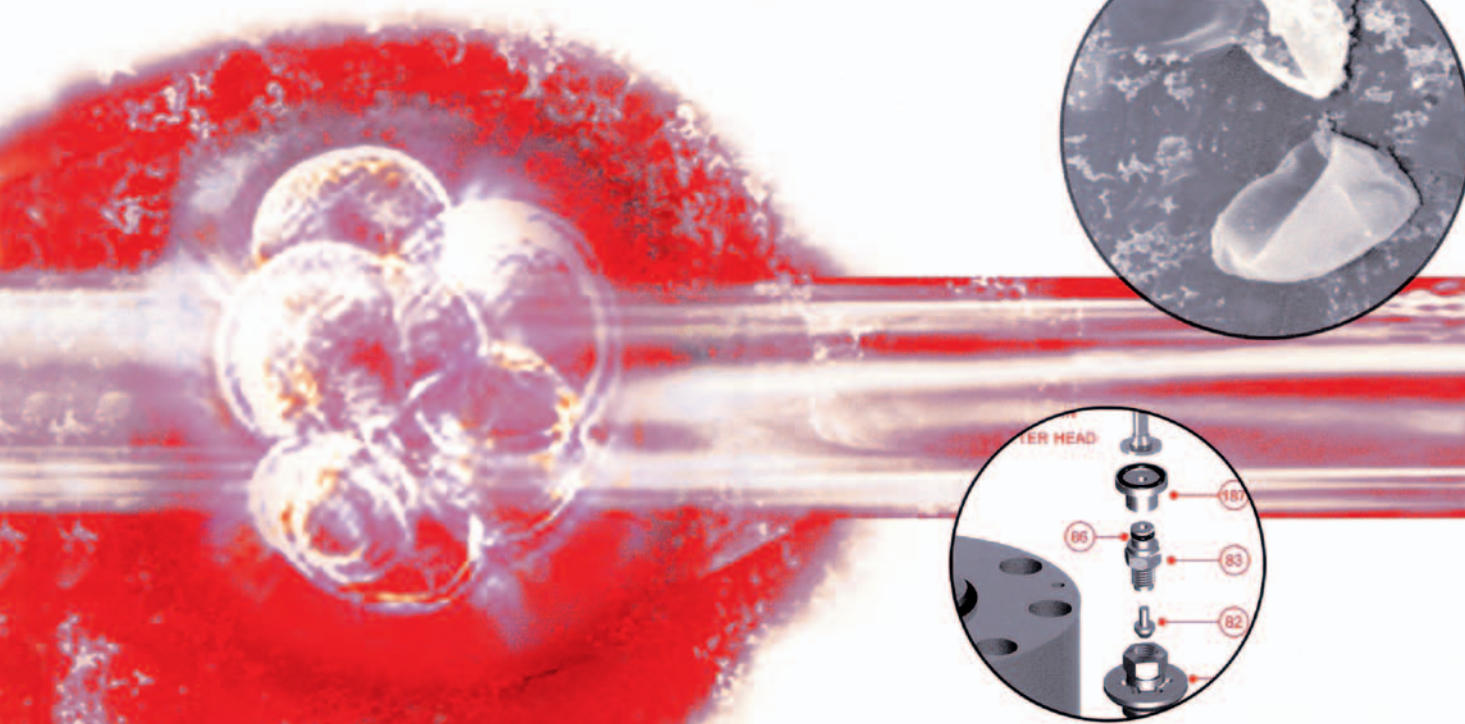
CONSTANT SYSTEMS LTD

# One Shot Cell Disrupters – Operator's Manual





## *CONSTANT SYSTEMS LIMITED*

# OPERATOR'S MANUAL

**For**

# *ONE SHOT CELL DISRUPTER*

**This Operating Manual Contains Important Safety Information**
**Read Thoroughly Before First Use.**
**Make Available To All Machine Users.**

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## DELIVERY METHOD STATEMENT

## FOR CONSTANT SYSTEMS LIMITED (CSL) MACHINES

1. **EXTREME CARE SHOULD BE TAKEN WHEN HANDLING OR MOVING CELL DISRUPTER MACHINES TO AVOID PERSONAL INJURY.**

2. THE CELL DISRUPTER WILL BE PALLETISED AND DELIVERED BY COURIER FOR INSTALLATION.

3. THE CLIENT IS RESPONSIBLE FOR THE UNLOADING OF PALLETISED MACHINES AND FOR TRANSPORTING THE PALLETISED MACHINE TO THE POINT OF USE.

4. AT THE POINT OF USE PALLETISED MACHINES SHOULD BE UNPACKED AND THE MACHINE TRANSFERRED TO THE WORKSTATION (OR, IF ORDERED, THE OPTIONAL BOLT-UP TROLLEY) BY MEANS OF A MANUAL LIFT.

5. MACHINE WEIGHTS ARE AS FOLLOWS
   *(approx for info only and add 40kg for palletised Bench Top machines)*

   | | |
   |---|---|
   | ONE SHOT MACHINE | 85kg |

   CRATE SIZES ARE AS FOLLOWS
   *width x depth x height in mm – approx for info only)*

   | | |
   |---|---|
   | ONE SHOT MACHINE | 850 x 760 x 1100 |

7. AFTER INSTALLATION, THE CLIENT IS RESPONSIBLE FOR THE SAFE REMOVAL OF ALL PACKAGING MATERIALS AND DISPOSAL IN AN ENVIRONMENTALLY ACCEPTABLE MANNER.

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Dear Customer.

Thank you for selecting a Constant Systems Cell Disrupter.

We would appreciate feedback on the performance of this machine. Please complete the following short survey document after at least two full months of operation (or fill in an on-line version at www.constantsystems.com)

1. Please score the performance of the machine out of a maximum top score of 10 for the following categories:-

    a. Ease of operation :

    b. Reliability :

    c. Overall Performance :

2. Please detail clearly any problems you have experienced/are experiencing with the machine:-

3. We would be delighted to hear any suggestions you may have for improving the operation or performance of the machine:-

4. Are there any additional functions you would wish to see added?

Thank you for taking the time to complete this form. Please return it to:

The IMS Manager
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UK

Or fax it to: ++44 (0) 1327 314147

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# A) INTRODUCTION

## What is Cell Disruption?

Cell Disrupter Systems are designed to selectively break the cell wall allowing intracellular components to be released and harvested. This is particularly for use in Pharmaceutical and Biotechnology companies, Universities, research institutes and agencies.

Cell Disruption is achieved through the use of high pressure which accelerates a sample through a small fixed orifice at high velocity under controlled, contained and repeatable conditions. There are three stages to the effective cell disruption:

1. The user manually loads the cell disrupter with the sample.

2. The piston then compresses the sample at a constant pressure, accelerating it through the small fixed orifice at high velocity. The acceleration of the product through this fixed orifice causes cell disruption.

3. When the jet containing disrupted cells hits the target, it is spread radially, then vertically down the cooled heat exchange surface of the cup. Product is then contained within the cup for collection by the user.

## Using the machine

The One Shot cell disrupter will enable you to work with quantities of material between 1 and 20.5 mls, depending on the maximum pressure ordered. There is sometimes a tiny amount of material not processed on the first stroke, being approximately 0.4 ml of dead volume. The One Shot cell disrupter will process material in fluid as well as non-flowing samples such as cell paste, plant leaves and tissue.

The equipment is used for bacteria, fungi, yeast, algae, plant and mammalian cells to disrupt cells, extract DNA, manipulate DNA and break down tissue. It is quick and easy to use, contained during operation and simple to clean.

## Using this manual

The drawings in this manual have all been collected together in Section H. When reading the pages which contain references to drawings, you may find it helpful to remove the page with the text and open the binder at the required drawing. In this way you will be able to look at both the drawing and its associated text at the same time.

Before proceeding with installation, please take time to read the information contained in this manual. It contains important safety, operational and maintenance information to help ensure that you get the best performance and long life from the machine.

This documentation satisfies all the requirements of the clauses of UL61010A-1.

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**Users are required to formally assess any and all risks associated with the processing of any sample materials prior to commencing work and are responsible for their own safety in this respect.**

## Alerts

In accord with common practice, three types of alert are used in this document:

- Warning (failure to observe could cause death or injury)
- Caution (failure to observe could cause damage to the equipment or process)
- Note (hint about how to make the work easier etc.)

Each alert declares which type it is.

**WARNING - Indicates a potentially hazardous situation, risk of electric shock, which if not avoided could result in death or serious injury.**

**WARNING - Indicates a potentially hazardous situation, in this case a biohazard, which if not avoided could result in death or serious injury.**

**WARNING - Surface temperature could rise to a potentially hazardous situation.**

**WARNING - Potential hazard of fire or combustion.**

**CAUTION - Indicates a potentially hazardous situation, which if not avoided, may result in minor or moderate injury.**

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## B) SAFETY CONSIDERATIONS

Various safety warning signs are attached to the machine. You must consult this documentation to read about the hazard in question, particularly where the (exclamation mark in triangle) appears.

**CAUTION - Be aware that power should be switched off when dismantling parts of the disruption head for maintenance (cleaning). Instruction to switch on the machine and later off again where this is necessary are included in the text.**

**CAUTION - If any work which involves dismantling any of the disruption head is to be done on the machine, the electrical supply must be isolated from the mains by the clients isolator.**

**WARNING - If the machine is used in any way that is not described in this document, the protection provided by the equipment may be impaired.**

**CAUTION - The loading and unloading of product into and from the machine is the responsibility of the user and the user is responsible for any controls which may be required to ensure that this loading and unloading is done safely and without undue risk to the health and safety of the user and/or other persons and/or the environment.**

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## C) INSTALLATION

### Environment

The machine is suitable only for indoor use in a clean, dry, dust and smoke free environment between 0°C and +40°C, at an altitude up to 2000M with maximum relative humidity of 80% up to +31°C decreasing linearly to 50% at +40°C.

### Location

**WARNING - Do not locate the machine in any way that makes it difficult to operate the disconnecting device (wall box).**

The machine must be set on a flat and level surface, positioned to allow access to the cable entry and a minimum space of 60mm each side for ventilation.

### Electrical (USA/Canada only)

The fitted power cable must be connected to the local mains supply by a qualified person by connecting the Brown Wire to Live; the Blue Wire to Neutral and the Green/Yellow Wire to PE/Ground using a 15 Amp fuse (ref. LP-CC-15-Bussmann or equivalent).

The machine shall be isolated by a lockable 1 or 2 pole isolator capable of switching 20 Amps which must be located as close to the equipment as possible according to local codes and regulations. A plug/socket combination **should not be used**.

### Electrical (Europe/Rest of the World)

A power cable with a moulded plug suitable for the local system is supplied for use with the machine.

### Aerosol and Product Containment

The liberation of aerosols and product into the atmosphere is prevented by internal sealing arrangements illustrated in DRG No 3D 1463 in section H. Nonetheless, venting may be required to prevent build up of pressure.

The two seals subjected to high pressure are marked A and B. In order for the sample to pass from chamber ‘C’ to chamber ‘D’ successfully, seals A and B must not leak.

In the event of seal B leaking, the product is contained during the cycle until the body is removed. If the leak were heavy the sample could be seen coming from the vent shown as B and G on DRG 3D CD 1463. In the event of seal A leaking the product would pass to vent A and F.

**WARNING - The sample must pass as aerosol to a kill tank if the substance is harmful.**

In the event of sample passing via vent H1 and H2, call a service technician.

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## D) GLOSSARY OF TERMS

| | |
|---|---|
| Aerosol | That part of the disrupted product that is in the form a gas. |
| Autoclaving | The process of cleaning/sterilising by application of compressed steam at a temperature of approximately 150°C. |
| Body | The outer casing of the disruption assembly which must be in place when a disruption cycle is taking place. |
| Cup | The container which collects the disrupted product. |
| Cycle | See Disruption Cycle |
| Dead Loss | The term used in the industry to describe the remnant which is left unprocessed. |
| Disruption Cycle | The process which begins when the probe is pressed and ends when the machine fires (audibly). Usually approximately 20 seconds. |
| Disruption Pressure | The pressure at which the sample is forced through the jet. This pressure persists for only a fraction of a second in each disruption cycle. |
| HP Seal | High pressure seal which forms the bottom of the cavity which holds the sample. It is driven upwards during a disruption cycle by the piston. |
| Input Cavity | A cylindrical cavity formed by the inside surface of the cylinder and the HP Seal at the bottom. |
| Jet | A sub-assembly in which a sapphire with a drilled hole of 0.18mm dia. is mounted in a stainless steel holder. The jet is fitted into the bottom of the cup. |
| Piston | The part which drives the HP Seal upwards to compress the sample during the disruption cycle. |
| Pressure | The word ‘pressure’ can have different meanings in this context. For operational use it is always qualified by the term ‘Disruption Pressure’. |
| Pressure Adjustment Knob | The circular knob on the front of the cabinet which adjusts the Disruption Pressure. |
| Probe | The rod which passes through the body and which is used to start a disruption cycle. |
| Slow Down | The ‘’SLOW DOWN” button provides a means of moving the piston, under manual control, to the bottom of its travel, usually for maintenance. The piston moves while the button is held pressed. When the piston has reached the bottom, the yellow PISTON DOWN light illuminates. |
| Slow Up | The ‘SLOW UP’ button provides a means of moving the piston, under manual control, to the top of its travel, usually for maintenance. The piston moves while the button is held pressed. It is used only when the HP Seal is visible. |

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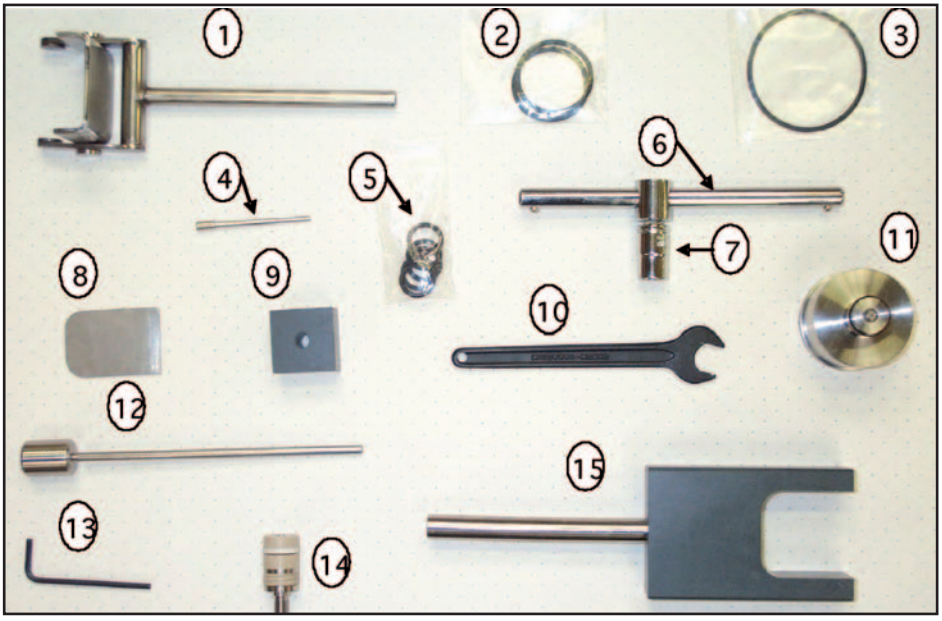
## F) TOOLS

### Photo Diagrams of Tools & Spares Kit




| ITEM | DESCRIPTION | ITEM NO | PART NO |
|---|---|---|---|
| Tool box | | | BO-1053 |
| Tools & Spares | Cup Lifting Tool | 1 | KE1324 |
| | O Ring Set (Shown as 2 & 3) | 2 | KE1742 |
| | Cup Lid O ring | 2 | BO-78 |
| | HP Cylinder O Ring | 2 | BO-78 |
| | Body O Ring | 3 | BO-305 |
| | Jet Removal Tool | 4 | KE1388 |
| | Cup O Ring x 10 (part of No. 11) | 5 | BO-73 |
| | 3/8” Tee Bar | 6 | BO-229 |
| | Socket 11mm A/F | 7 | BO-232 |
| | Cup Lid Lever | 8 | KE1435 |
| | Jet Removal Block | 9 | KE1741 |
| | Flat Ground 14 A/F Spanner | 10 | KE1468 |
| | Cup With Jet | 11 | KE2703 |
| | Cup Lid with O-Ring (Fitted to No.11) | | KE1255 |
| | Operating Probe | 12 | KE1395 |
| | 3mm Allen Key | 13 | BO-140 |
| | HP Seal | 14 | KE2701 |
| | HP Cylinder Lifting Block | 15 | KE1474 |
| | User Manual (Not Shown) | | KE2656 |

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## G) OPERATION

### Overview Sequence of Operation

As the name implies, the “One Shot” machine requires all the samples to be input and removed from the machine individually. Assuming that a sample has just been disrupted and removed from the machine, an overview of the operational sequence would be:

1. Ensure that the PISTON DOWN lamp is ON
2. Pipette the sample into the hole in the top of the cylinder
3. Fit the cup (with lid on) into the top of the cylinder to collect the output
4. Fit the Body and insert the Probe
5. Press and hold the probe until the machine fires (audibly)
6. Remove the Body and remove the sample which has collected in the cup

### Detailed Sequence of Operation

This is a complete list of all operations although the ones that are indicated as “Only for start up” (or similar) will not need to be repeated for every sample if the machine is in constant use.

1. Ensure that the Probe is not in the machine.
2. (Only for start up) Switch on the power at the isolator/switch (as applicable).
3. Remove the body. Rotate it until it is possible to lift the body away from the machine. This is illustrated on DRG 3D 1243 Sheet 1.
4. Remove the cup using the Cup Lifting Tool illustrated on DRG 3D 1243 Sheet 2. The cup may be warm if the machine has been in constant use for some time but it is never dangerously hot.
5. Check that the cup is empty. To do this remove the lid using the Lid Lever and inspect the inside of the cup.

**CAUTION - It is the responsibility of the user to ensure the cleanliness of the input cavity, the cup and the lid. Observe any local or in-house regulations concerning cleanliness and autoclave or sterilise the HP Seal, cylinder, cup and lid as necessary..**

6. (Only if necessary) The Dead Loss remains in the input cavity after the disruption cycle. If it is important that the input cavity is cleaned before the next disruption, follow the procedure entitled “Removal and Replacement of the HP Seal” in the Maintenance section. Clean the HP Seal, cylinder, cup and lid.

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**CAUTION - Do not fit the cup without the lid.**

7. Ensure that the PISTON DOWN lamp is illuminated and that the PRESSURE SETTING indicator shows the desired pressure. If the PISTON DOWN lamp is not illuminated, press and hold the SLOW DOWN button until it illuminates.

8. (Only if necessary) Adjust the pressure using the knob on the front of the cabinet.

9. Pipette an appropriate volume of the sample into the hole in the top of the cylinder. Ensure that the chamber is not overfilled because this would prevent the cup and lid from fitting properly.

10. Fit the cup (with lid on) into the top of the cylinder to collect the output.

11. Place the Body over the cylinder and lower it down to the surface on which it will rest. Rotate it until it drops on to the surface and rotate it again to align the marks with each other. The marks are illustrated on DRG 3D 1243 Sheet 1 (in the callout). This last step is necessary to be able to insert the probe.

12. Insert the probe.

**CAUTION - At the next step, ensure that the probe is held pressed until the PISTON DOWN lamp extinguishes AND ILLUMINATES AGAIN. Failure to observe this caution will abort the disruption cycle prematurely.**

13. Press the probe downwards and hold it until you hear the machine fire (not a loud noise), the PISTON DOWN lamp extinguishes and re-illuminates.

14. Release and then remove the probe. The piston will have automatically returned to its lowest point and the disruption cycle is complete.

15. Remove the Body by turning it and lifting it clear of the cylinder.

16. Remove the cup from the top of the cylinder using the Cup Lifting Tool.

17. Remove the lid from the cup using the Cup Lid Lever. The disrupted sample can now be removed form the cup.

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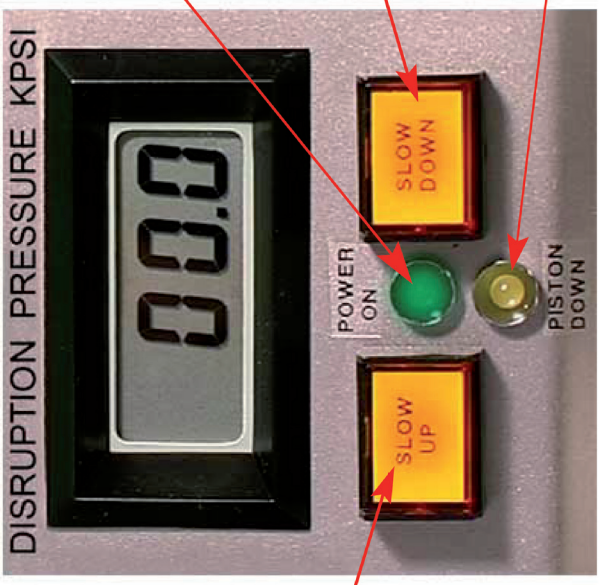
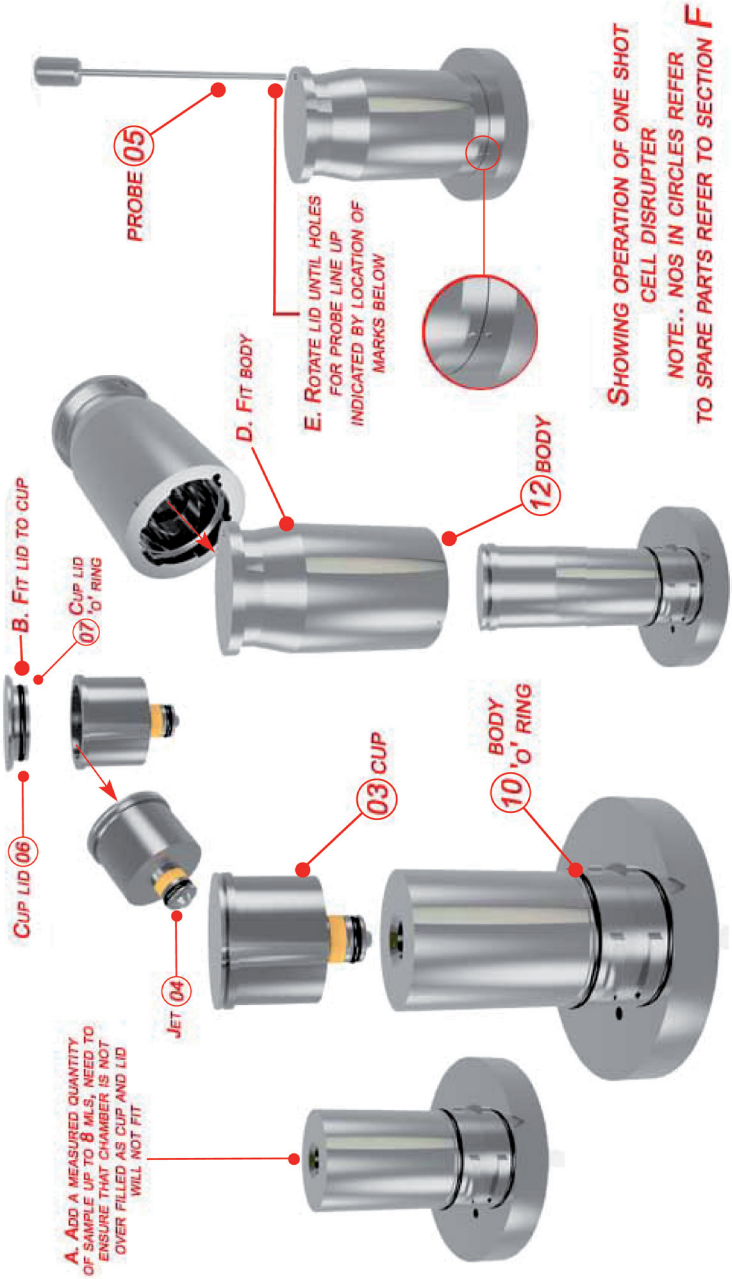
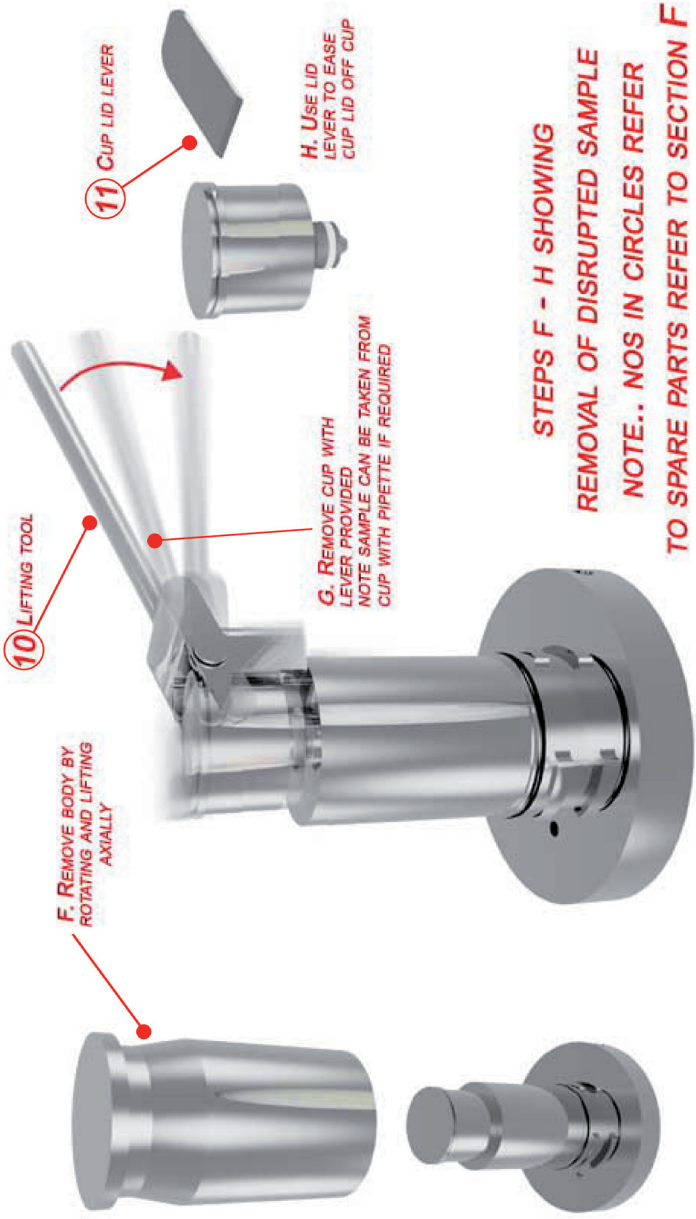

DISRUPTION PRESSURE KPSI
0.0
POWER ON
SLOW DOWN
SLOW UP
PISTON DOWN
Power On Lamp
Press to move operating piston down slowly use when piston down light does not indicate that piston is fully down
Piston Down Lamp
Press to move operating pistonup slowly. Use when changing HP seal and when removing HP cylinder for cleaning


A. Add a measured quantity of sample up to 8 mls, need to ensure that chamber is not over filled as cup and lid will not fit
Jet 04
Cup lid 06
B. Fit lid to cup
Cup lid 'O' ring 07
D. Fit body
E. Rotate lid until holes for probe line up indicated by location of marks below
Probe 05
Body 12
Body 'O' ring 10
Cup 03
Showing operation of one shot cell disrupter
NOTE.. nos in circles refer to spare parts refer to section F

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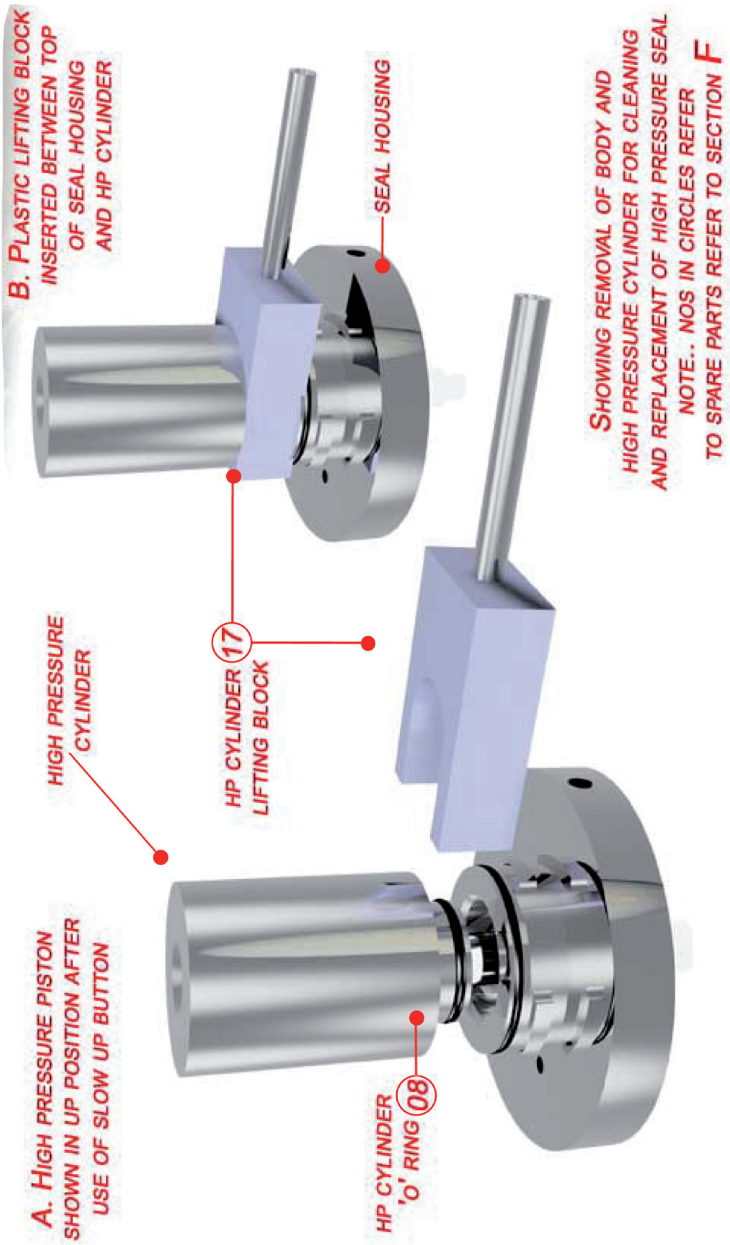
B. PLASTIC LIFTING BLOCK INSERTED BETWEEN TOP OF SEAL HOUSING AND HP CYLINDER
SEAL HOUSING
SHOWING REMOVAL OF BODY AND HIGH PRESSURE CYLINDER FOR CLEANING AND REPLACEMENT OF HIGH PRESSURE SEAL NOTE.. NOS IN CIRCLES REFER TO SPARE PARTS REFER TO SECTION F
HIGH PRESSURE CYLINDER
HP CYLINDER 17 LIFTING BLOCK
A. HIGH PRESSURE PISTON SHOWN IN UP POSITION AFTER USE OF SLOW UP BUTTON
HP CYLINDER 'O' RING 08

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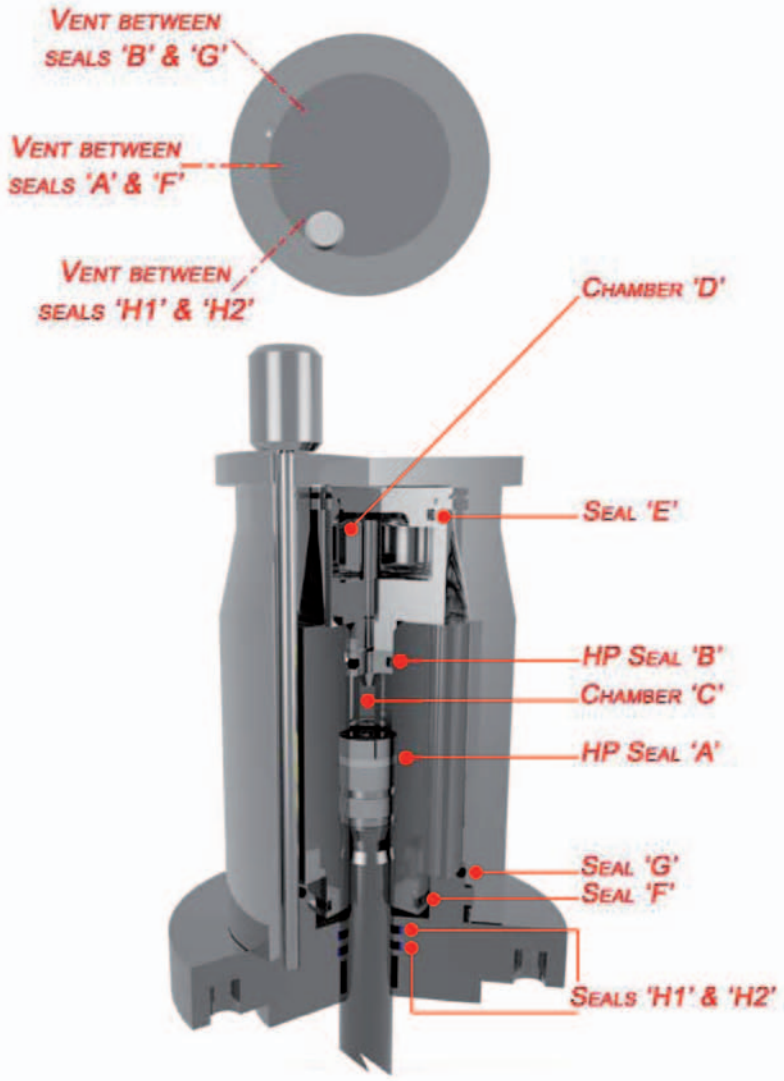


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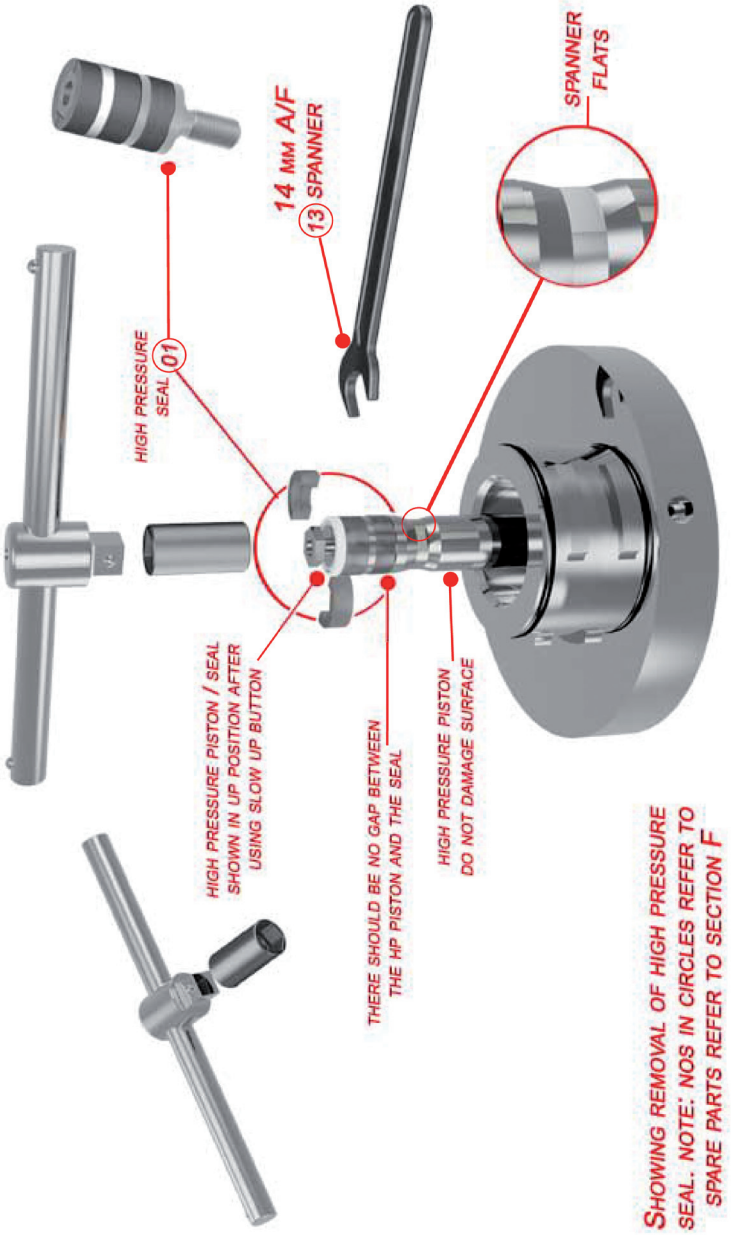
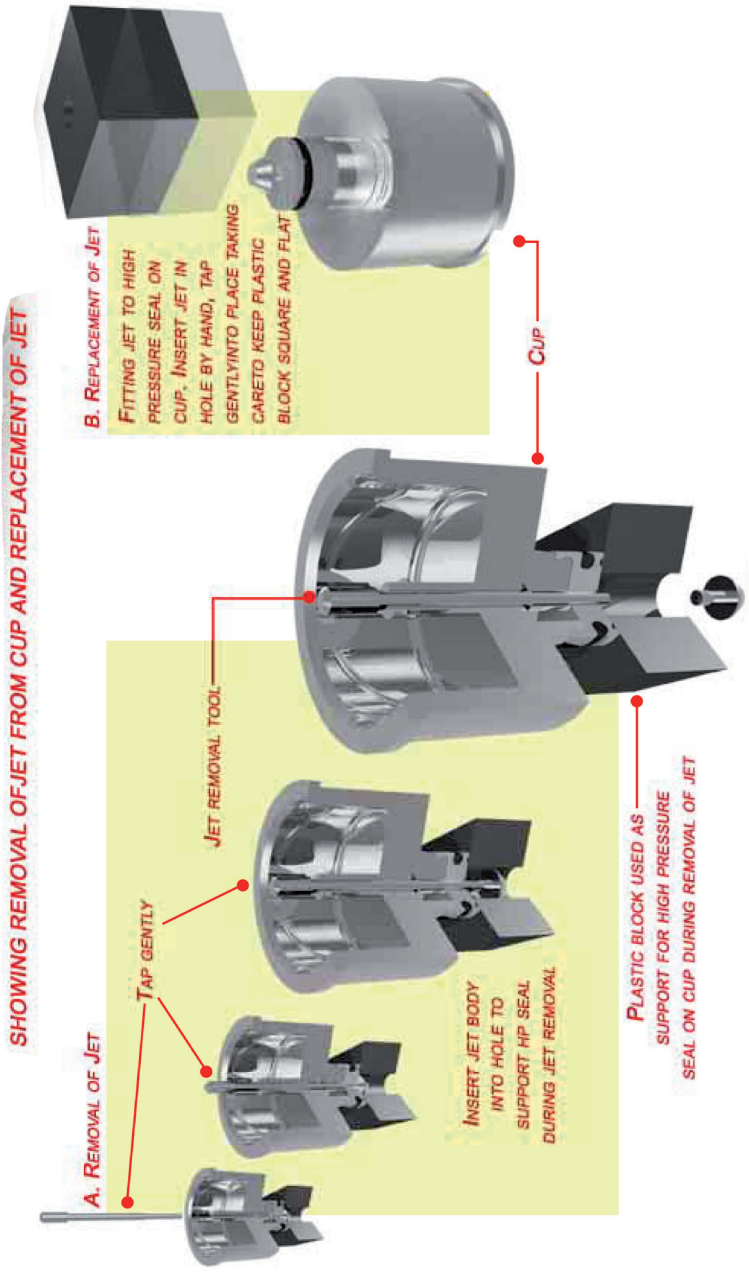

14 MM A/F
13 SPANNER
SPANNER FLATS
HIGH PRESSURE SEAL 01
HIGH PRESSURE PISTON / SEAL SHOWN IN UP POSITION AFTER USING SLOW UP BUTTON
THERE SHOULD BE NO GAP BETWEEN THE HP PISTON AND THE SEAL
HIGH PRESSURE PISTON DO NOT DAMAGE SURFACE

SHOWING REMOVAL OF HIGH PRESSURE SEAL. NOTE: NOS IN CIRCLES REFER TO SPARE PARTS REFER TO SECTION F


SHOWING REMOVAL OFJET FROM CUP AND REPLACEMENT OF JET
A. REMOVAL OF JET
TAP GENTLY
JET REMOVAL TOOL
INSERT JET BODY INTO HOLE TO SUPPORT HP SEAL DURING JET REMOVAL
PLASTIC BLOCK USED AS SUPPORT FOR HIGH PRESSURE SEAL ON CUP DURING REMOVAL OF JET
CUP
B. REPLACEMENT OF JET
FITTING JET TO HIGH PRESSURE SEAL ON CUP. INSERT JET IN HOLE BY HAND, TAP GENTLYINTO PLACE TAKING CARETO KEEP PLASTIC BLOCK SQUARE AND FLAT

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## J) MAINTENANCE

All the following maintenance procedures are routinely carried out at the recommended 6-monthly service of the machine. Additionally any of them can be carried out on site for cleaning and decontamination purposes (for example when changing samples).

### Removal and Replacement of the HP Seal

To remove the HP Seal it is necessary first to remove the cylinder.

### To Remove the Cylinder

1. Ensure the probe is not in the machine.

2. Remove the Body.

3. At the end of the last disruption cycle the piston will have returned to the bottom of its travel. Press SLOW UP and the piston will lift the cylinder up to the top of its travel. This is illustrated at DRG 3D 1244.

4. Insert the Cylinder Lifting Block in the gap and press (and hold) the SLOW DOWN button until the amber lamp comes on; then release. This will pull the piston downwards out of the cylinder which can then be lifted away from the machine.

### To Remove the HP Seal

**CAUTION - Take great care not to have fingers near to the hp cylinder or seal housing**

1. When the cylinder has been removed, the HP Seal and piston are visible. Drive the piston to the top using the SLOW UP button. Release the button when the piston stops moving. (It will fall back slightly; this is normal).

2. Switch off the power supply at the isolator. This is essential to avoid the possibility of damage at the next step.

3. Fit the 14mm open-ended piston spanner on the flats on the piston shaft. You will later need to hold this spanner to prevent the piston shaft from rotating.

4. Hold the open-ended piston spanner (to prevent the piston shaft from rotating) and turn the T-bar anti-clockwise to unscrew the HP Seal from the piston shaft.

5. The HP Seal can now be cleaned, sterilised or renewed according to local procedures.

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## To Replace the HP Seal

1. Ensure that the HP Seal and HP Piston mating faces are clean and then screw the HP Seal back into the piston by hand until the faces meet.

2. Fit the 14mm open-ended piston spanner on the flats on the piston shaft.

3. Prevent the piston shaft from turning using the open-ended spanner and turn the arms of the T-bar clockwise to tighten the HP Seal.

4. Remove the T-bar and socket.

5. Remove the 14mm open-ended spanner from the piston shaft. Replace the two part retainer clip.

6. Reconnect or switch on the power supply.

7. Press SLOW DOWN until the PISTON DOWN lamp illuminates.

## To Refit the Cylinder

Press the cylinder down over the HP Seal carefully ensuring that no damage takes place to the seal.

## Removal and Replacement of the Jet

The jet consists of a 0.18mm dia hole drilled in sapphire which is mounted in stainless steel. It does not wear out and becomes blocked only when solid matter (for example glass shards or particles of plastic) obstruct or partially obstruct the orifice by becoming lodged in it. A blocked jet must be replaced with a new one. The jet is an interference-fit in the base of the stainless steel cup.

The procedure for Removal and Replacement of the Jet is illustrated on DRG 3D 1473.

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## To Remove the Jet from the Cup

1. Place the Jet Removal Holder on a firm workbench.
2. Place the cup on the holder so that the jet fits into the hole.
3. Insert the Jet Removal Tool into the pipe in the cup and tap it with a nylon or brass mallet. Tap it hard enough to push out the jet.

## To Fit a New Jet

1. Place the cup with base uppermost on a firm workbench.
2. Place the new jet part way into the hole in the base of the cup. It will fit easily for a short distance.
3. Using the Jet Removal Holder on its side (that is, with the hole horizontal) as a protector, tap the Jet Removal Holder as hard as necessary to drive the jet into the base of the cup. It should go fully into the cup until only the cone part is visible.

## Removal and Replacement of the EDPM O-Ring

**NOTE - Under NO circumstances use any metal or abrasive items to assist in the removal of the EPDM O-ring.**

The expected life of the cup O-Ring before leakage is approximately 100 cycles. To replace the O-Ring:

1. Using the thumb and forefinger, squeeze the O-Ring to make it protrude to one side.
2. Roll the O-Ring off the jetthe cup.

Fitting of a new O-Ring is the reverse of the above procedure. Ensure that the O-Ring is properly seated and not twisted in the groove.

**NOTE - On initial few cycles of this cup there may be small fragments of the EPDM O-Ring escaping into the product or remaining in the cylinder. However, these are not detrimental to the product or process. Should you find these fragments problematic for your application please run the cup using water for the first 10 cycles.**

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## K) TROUBLESHOOTING

1. No power (e.g. digital panel meter does not illuminate and power on light not showing)

   Not plugged in
   Not switched on
   Fuse faulty in plug or circuit breaker out
   Trip on front of panel
   DPM faulty (DPM = Digital Panel Meter)
   Faulty power on LED

2. Digital display does not illuminate

   Check power is applied to machine
   24V DC power supply failed
   Contact service agent

3. Pressure control knob does NOT change digital display

   Knob loose on spindle
   Control potentiometer faulty
   24V DC power supply faulty
   Display faulty
   Contact Service Agent

4. Pressure cycle not completed within 50 seconds of machine being started

   Solenoid failure - contact Service Agent
   Solenoid valve failure - contact Service Agent
   Blocked jet - increase pressure setting to clear jet, if this does not help see Section D. Jet and Cup Assembly

5. Sample present under Cup or showing in telltales

   Replace cup and seal assembly.

6. No throughput of sample and stroke does not complete

   Try increasing pressure setting: if this doesn't help
   Replace the blocked jet

7. Seals and Leaks

   Refer to ‘Remove the HP Seal’ under Maintenance.

FOR SERVICE CALL YOUR SUPPLYING AGENT.:

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## L) SPECIFICATION FOR 'ONE SHOT' CELL DISRUPTER

The 'One Shot' machine incorporates our unique disruption head and hydraulic operating and control components. The disruption head is mounted in a stainless steel tray to avoid spillage. The disruption head is easily dismantled for manual cleaning and pre-cooling. The 'One Shot' machine allows loading of solid sample, cell paste or suspended sample.

QUANTITIES: Quantity of sample that can be processed in each shot is dependant on the pressure rating of the machine and disruption head purchased. These are shown in the table below.

| | |
|---|---|
| 40kPSI | 1-8mls |
| 30kPSI | 1-10.5mls |
| 20kPSI | 1-16mls |
| 10kPSI | 1-20mls |

PROCESS TIME: Manual loading of each shot takes approx 2 minutes. It takes approx 30 seconds for the machine to operate and complete the disruption of the sample

POWER REQUIRED: See Section C and rating plate on machine

COOLING: No provision is made for cooling but the removable parts can be pre-cooled so as to use the cooling capacity of the metal parts

CONTROL SYSTEM: Pressure control allows the disruption pressure to be accurately pre-set before starting cycle. Single push button control of disruption cycle

SAFETY: Disruption cycle inactivated if head assembled incorrectly Secondary pressure containment

MAINTENANCE: Jet, seal and target easily changed by non-technical personnel with tools supplied

HYDRAULIC OIL, ISO32: Store under cover away from heat and a source of ignition. Wear gloves and eye protection when handling or filling reservoir. Ensure no oil spills on to electrical equipment. Clean up any other spills immediately.

Disposal should be in accordance with local regulations and any environmental protection act.

SPARES: All components should be supplied by CSL or authorised agents.

OPTIONS: Stainless steel trolley/stand

SIZE W/D/H/: 510mm x 440mm x 385mm

MATERIAL: Stainless steel

SUPPLIED WITH: Operating manual
One set of consumable spares
Tools

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E–mail: constant@score-group.com
Website: www.constantsystem.com

## EC DECLARATION OF CONFORMITY

We Constant Systems Ltd under our sole responsibility declare that the product as listed below

**PRODUCT CATEGORY:** **CELL DISRUPTER**
**MODEL:** **ONE SHOT**

conforms with principal safety objectives of the European Directive 97/23/EC (Pressure Equipment Directive') in accordance with conformity assessment procedure: Module A

The pressure equipment constituting the Pressure Equipment Assembly consists of the following: Disrupter Pump (Category 1), Accumulator (Article 3.3-SEP), & Hydraulic Operating Circuits (Article 3.3 – SEP)

Conforms with principal safety objectives of the European Directive 73/23/EC ('Low Voltage Directive')

Conforms with the protection requirements of European Directive 89/336/EC ('EMC Directive')

This certificate also confirms that all tests specified in our build instructions have been satisfactorily completed.

The machine should at all times be operated as instructed in the Operating Manual.

Signed:

Robert Sinclair

Title: IMS Manager

On Behalf Of Constant Systems Ltd

Date: MAY 2007

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Intertek ETL SEMKO

## AUTHORIZATION TO MARK

This authorizes the application of the Certification Mark(s) shown below to the models described in the Product(s) Covered Section when made in accordance with the conditions set forth in the Certification Agreement and Listing Report. This authorization also applies to multiple listee model(s) identified on the correlation page of the Listing Report.

**Applicant:** Constant Systems Limited
Low March, Daventry
Northants. NN11 4SD, United Kingdom

**Contact:** Name: Mr Bob Sinclair Phone: +44 (0) 1327 314 146
Fax: +44 (0) 1327 314 147

**Manufacturer** Same as Applicant

**Party Authorised to Apply Mark:** Same as Manufacturer

**Report Issuing Office:** Intertek ETL SEMKO, Leatherhead, U.K.

**Report No.:** 05016948

**Product Covered:** One Shot series models O0/15/BA, O0/20/BA, O0/30/BA and O0/40/BA.
TS2 series models TS2/15/BA/AA, TS2/20/BA/AA, TS2/30/BA/AA and TS2/40/BA/AA.
TS5 series models TS5/15/EE/GA, TS5/15/EB/GA and TS5/15/EC/GA.
TS5 series models TS5/20/EE/GA, TS5/20/EB/GA and TS5/20/EC/GA.
TS5 series models TS5/30/EE/GA, TS5/30/EB/GA and TS5/30/EC/GA.
TS5 series models TS5/40/EE/GA, TS5/40/EB/GA and TS5/40/EC/GA.
TS6 series models TS6/15/BA/AA, TS6/15/EE/GA, TS6/15/EB/GA and TS6/15/EC/GA.
TS6 series models TS6/20/BA/AA, TS6/20/EE/GA, TS6/20/EB/GA and TS6/20/EC/GA.
TS6 series models TS6/30/BA/AA, TS6/30/EE/GA, TS6/30/EB/GA and TS6/30/EC/GA.
TS6 series models TS6/40/BA/AA, TS6/40/EE/GA, TS6/40/EB/GA and TS6/40/EC/GA.
TS7 series models TS7/15/EE/GA, TS7/15/EB/GA and TS7/15/EC/GA.
TS7 series models TS7/20/EE/GA, TS7/20/EB/GA and TS7/20/EC/GA.
TS7 series models TS7/30/EE/GA, TS7/30/EB/GA and TS7/30/EC/GA.
TS7 series models TS7/40/EE/GA, TS7/40/EB/GA and TS7/40/EC/GA.

**Description:** Cell Disrupter Systems

**Standard(s):** Electrical Equipment for Laboratory Use; Part 1: General Requirements UL 61010A-1, 1st Edition 2002, including revision 6th December 2002 and
Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements
CAN/CSA-C22.2 No. 1010.1-92, including amendment 2; February 1997, R1999

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Authorised by: _____ Date: 29 March 2007
Gunilla Lindström for
William T Starr, Certification Manager

Control Number: 3092407

This document supersedes all previous Authorisations to Mark for the noted Report Number.

Intertek Testing Services NA Inc.
165 Main Street, Cortland, NY 13045
Telephone 800-345-3851 or 607-753-6711 Fax 607-756-6699

MMB

## CONSTANT SYSTEMS CELL DISRUPTER LOG BOOK

| DATE | TIME | NAME | PRESSURE | VOLUME | ORGANISM | COMMENTS |
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